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Paper 94
Filed: December 21, 2010

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Advanced Research and Technology Institute, Inc.
Junior Party
(U.S. Patent Applications 08/948,764, 08/955,572 and 10/027,199).

v.

Immunex Corporation
Senior Party
(U.S. Patent 7,211,259),

Patent Interference No. 105,662 (MPT)
(Technology Center 1600)

Judgment - Bd.R. 127

Before: RICHARD TORCZON, SALLY GARDNER LANE, and MICHAEL P. TIERNEY, *Administrative Patent Judges*.

TIERNEY, *Administrative Patent Judge*.

The Board has entered a Decision on Priority in this interference. (Paper 93). Pursuant to the panel decision on priority, it is:

ORDERED that judgment as to the subject matter of Count 1 (Paper 1 at 4) is entered against ARTI's U.S. Patent Applications 08/948,764, 08/955,572 and 10/027,199.

FURTHER ORDERED that ARTI's involved claims, '572 claims 5-6, 24 and 26-31, '764 claims 19-24, 26 and 28-36 and '199 claims 1, 19 and 21-23 are FINALLY REFUSED, 35 U.S.C. § 135(a);

FURTHER ORDERED that the parties shall note the requirements of 35 U.S.C. § 135(c) and Bd. R. 205; and

FURTHER ORDERED that a copy of this judgment be entered in the administrative records of the involved ARTI applications and Immunex patent.

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Immunex Corporation
Senior Party
(U.S. Patent 7,211,259),

Patent Interference No. 105,662 (MPT)
(Technology Center 1600)

Decision – Priority Date – Bd.R. 125(a)

Before: RICHARD TORCZON, SALLY GARDNER LANE, and MICHAEL P. TIERNEY, *Administrative Patent Judges*.

TIERNEY, *Administrative Patent Judge*.

I. Introduction

This interference is before a merits panel for a decision on priority motions regarding Count 1, the sole count in interference. Generally, Count 1 is directed to polypeptides, H4-1BB, and DNA sequences encoding the polypeptides. H4-1BB polypeptide is now recognized as a member of the tumor necrosis factor (TNF) receptor super-family. (AX 2002, 2:46-51).

Both parties filed motions for judgment on priority of invention, Immunex Motion for Priority (Paper 86) and ARTI Motion for Priority (Paper 83). The parties however, have entered into a settlement agreement whereby neither party filed an opposition or reply and neither party cross-examined their opponent's witnesses. (Order, Paper 89). As such, the parties' priority motions are unopposed.

ARTI is junior party in the interference and bears the burden of proving priority of invention. This burden exists even when the motion is not opposed.

ARTI's motion for priority alleges that ARTI was the first to have conceived and actually reduced to practice the subject matter of Count 1. (Paper 83, 1:13-23). Additionally, ARTI appears to allege conception combined with diligence to a later reduction to practice as ARTI states as fact that its inventor, Dr. Kwon, worked diligently on his H4-1BB project up until the time it was constructively reduced to practice. (*Id.*, 17:20-22).

Based on the record presented, we hold that ARTI has presented sufficient and credible evidence that it conceived an embodiment within the scope of Count 1 prior to Immunex's accorded priority benefit date. ARTI however, has failed to establish that tests were conducted to demonstrate that its H4-1BB compounds worked for a specific and practical utility. Additionally, ARTI has failed to demonstrate diligence to a later reduction to practice as ARTI did not identify a

sufficient daily/weekly/monthly timeline of events regarding the work on its H4-1BB project. Accordingly, we enter judgment on priority of invention against junior party ARTI.

II. Findings of Fact

The record supports, by a preponderance of the evidence, the following findings:

A. Accorded Priority Benefit

1. Junior Party ARTI

1) ARTI is accorded an earlier constructive reduction to practice (*i.e.*, benefit for the purpose of priority) of U.S. Application 08/122,796, filed September 16, 1993. (Decision, Paper 80, 5).

2. Senior Party Immunex

2) Immunex has been accorded an earlier constructive reduction to practice (i.e., benefit for the purpose of priority) of U.S. Application 08/060,843, filed May 7, 1993. (*Id.* at 6).

C. The Count and Claim Correspondence

3) There is a single count in the interference, Count 1, which reads as follows:

> A compound according to claims 7 or 16 of U.S. Patent 7,211,259 or according to claim 24 of U.S. Application 08/955,572 or claim 1 of U.S. Application 10/027,199.

(Paper 1, p. 4).

4) Generally, the claims identified in Count 1 relate to polypeptides for human

4-1BB (ARTI SEQ ID NO: 2 and Immunex SEQ ID NO: 8) and DNA sequences encoding the polypeptides. For example, claim 16 of Immunex '259 and claim 24 of ARTI '572 form a part of Count 1 and read as follows:

> 16. A purified polypeptide selected from the group consisting of polypeptides comprising amino acids 1-163 of SEQ ID NO: 8 and polypeptides comprising a fragment of amino acids 1-163 of SEQ ID NO: 8, the fragment being capable of binding a 4-1BB-L.
>
> 24. A purified soluble H4-1BB polypeptide, wherein said polypeptide comprises the extracellular domain of SEQ ID NO: 2 or a fragment of the extracellular domain which is capable of specifically binding a cell membrane ligand for SEQ ID NO: 2.

5) Amino acids 1-163 of Immunex SEQ ID NO: 8 and amino acids 24-186 of ARTI SEQ ID NO: 2 represent the extracellular domain portion of H4-1BB. (Declaration of Nigel Killeen, IX 1015, ¶¶ 14 and 44).

6) The claims of the parties are:

Immunex '259:	1-19
Advanced Research and Technology Inst. '572:	5-6, 24, 26 and 27-31
Advanced Research and Technology Inst. '764:	19-24 and 26-36
Advanced Research and Technology Inst. '199:	1-3 and 19-23

(Declaration, Paper 1, p. 4).

7) The claims of the parties which correspond to Count 1 are:

Immunex '259:	1-2 and 6-19
Advanced Research and Technology Inst. '572:	5-6, 24 and 26-31
Advanced Research and Technology Inst. '764:	19-24, 26 and 28-36
Advanced Research and Technology Inst. '199:	1, 19 and 21-23

(*Id).*

8) The claims of the parties which do not correspond to Count 1, and therefore are not involved in the interference, are:

Immunex '259:	3-5
Advanced Research and Technology Inst. '572:	None
Advanced Research and Technology Inst. '764:	27[1]
Advanced Research and Technology Inst. '199:	2, 3 and 20

(*Id).*

ARTI's Priority Evidence

9) ARTI's priority motion relies upon testimony from three declarants:

i) Dr. Byoung S. Kwon, the sole named inventor of ARTI's involved applications (AX 2107);

ii) Dr. Kack Kyun Kim, a visiting scientist in Dr. Kwon's laboratory (AX 2122); and,

iii) Dr. James L. Riley, a person of ordinary skill in the art at the time of the invention who testifies as to how one skilled in the art would interpret Dr. Kwon and Dr. Kim's laboratory notebooks (Riley Declaration AX 2117, Laboratory notebooks, including AX 2126).

Conception

10) Dr. Kwon testifies that, in the 1980's, he was searching for new ways to treat human diseases associated with the immune system. (AX 2107, ¶ 5).

11) Dr. Kwon testifies that he was the first person to isolate and sequence mouse 4-1BB. (*Id.*, ¶ 5).

[1] '764 claim 27 depends from previously cancelled claim 25.

12) Dr. Kwon testifies that he performed experiments on mouse 4-1BB and determined that it was a T-lymphocyte mediator and that he recognized the potential importance of a T-lymphocyte inducible gene product, such as 4-1BB, in the regulation of the immune system. (*Id.*, ¶¶ 6, 10-11).

13) Dr. Kwon states that by mid-1990 he was pursuing the human homologue of mouse 4-1BB. (*Id.*, ¶ 13).

14) Dr. Kwon testifies that in 1991-92 he had a large laboratory with many scientists and that Dr. Kim worked in his lab as a visiting scientist from Korea. (*Id.*, ¶ 36).

15) Dr. Kwon states that he appreciated in 1991-92 that H4-1BB was a receptor protein and that the portion residing outside the cell membrane, the extracellular domain, was important to its function and that the H4-1BB ligand likely bound the H4-1BB extracellular domain. (*Id.*, ¶ 40).

16) Dr. Kwon testifies that he was excited to have Dr. Kim arrive in winter 1991 as Dr. Kwon was eager to begin working on expression of the human 4-1BB ("H4-1BB") protein and that he wanted Dr. Kim to prepare a construct for making a fusion protein comprising the extracellular domain of H4-1BB. (*Id.*, ¶¶ 36-38).

17) Dr. Kwon testifies that Dr. Kim worked in the laboratory from December 20, 1991 until January 16, 1992 and that while at the laboratory Dr. Kim used bacterial human 4-1BB cDNA producing clones to help generate a H4-1BB fusion protein containing the H4-1BB extracellular domain. (*Id.*, ¶ 39).

18) According to Dr. Kwon, on January 7, 1992 he wrote down on a notepad page (AX 2126) the specific primers to be used to amplify portions of H4-1BB cDNA from full length H4-1BB. (AX 2107, ¶ 42).

19) Dr. Kwon states that he instructed Dr. Kim to utilize the PCR product obtained from the specific forward and reverse H4-1BB primers to begin constructing the H4-1BB fusion protein that contained the H4-1BB extracellular domain. (*Id.*, ¶ 48).

20) According to Dr. Kwon, Dr. Kim produced the requested H4-1BB fusion protein as evidenced by Dr. Kim's notebook page dated January 15, 1992, which Dr. Kwon recognizes as containing Dr. Kim's handwriting (AX 2125). (AX 2107, ¶ 49).

21) Dr. Kim testifies that he visited Dr. Kwon's laboratory from December 20, 1991 to January 16, 1992 and while there he worked on making a fusion protein comprising the extracellular domain of H4-1BB. (AX 2122, ¶¶ 8-12).

22) According to Dr. Kim, prior to his arrival, Dr. Kwon's laboratory had already isolated, sequenced, inserted into a cloning vector and transferred H4-1BB cDNA to bacteria. (*Id.*, ¶ 9).

23) Dr. Kim testifies that he is familiar with Dr. Kwon's handwriting and that AX 2126 reflects Dr. Kwon's handwriting and depicts the specific PCR primers for amplifying portions of H4-1BB cDNA from the bacterial clones maintained in Dr. Kwon's lab. (*Id.*, ¶ 13).

24) Dr. Kim testifies that AX 2125 is a true and accurate copy of his laboratory notebook pages where he recorded his experiments while visiting Dr. Kwon's lab in December 1991 to January 1992 and that as indicated by the notebook, he utilized Dr. Kwon's PCR primers to begin constructing the H4-1BB fusion protein. (*Id.*, ¶ 16).

25) Dr. Kim testifies that the cloning was successful and that the vector was later inserted into an expression vector that produced the H4-1BB protein. (*Id.*, ¶ 19).

26) Dr. Riley testifies that, given the universe of possible primer sequences, the specific primers identified in Dr. Kwon's handwritten note (AX 2126) leads to the inescapable conclusion that Dr. Kwon had previously isolated the full-length H4-1BB cDNA sequence and possessed the complete nucleic sequence encoding H4-1BB by at least January 7, 1992. (AX 2117, ¶¶ 31 and 41-44).

Actual Reduction to Practice

27) Dr. Kwon provides the following testimony regarding his testing of the H4-1BB extracellular domain and H4-1BB cDNA:

> 50. After cloning human 4-1BB, I used human 4-1BB cDNA to study transcription of human 4-1BB in T-cells.
>
> 51. After cloning human 4-1BB, I used human 4-1BB protein to generate antibodies selective for the extracellular domain of human 4-1BB.
>
> 52. After cloning human 4-1BB, I used the APtag fusion protein to conduct human 4-1BB ligand binding studies.

(AX 2107, ¶¶ 50-52).

Diligence

28) Dr. Kwon provides the following testimony regarding his diligence towards filing his '796 application on September 16, 1993:

> 53. I continued to work diligently on my 4-1BB projects up until the time I filed U.S. Patent Application Serial Number 08/122,796 on September 16, 1993.
>
> 54. In the winter of 1992-1993, I and other members of my laboratory began drafting a manuscript that was submitted to Immunology Letters on October 12, 1994. The manuscript includes a discussion of our isolation of human 4-1BB cDNA.

(AX 2107, ¶¶ 53-54).

III. Opinion

An interference is a procedure to determine who among competing parties was the first to invent a commonly claimed invention. 35 U.S.C. §§ 102(g) and 135(a). The commonly claimed invention in interference is generally directed to purified H4-1BB polypeptides and DNA sequences encoding the polypeptides where the polypeptides comprise the H4-1BB extracellular domain.

Both parties have filed motions for judgment on priority of invention. ARTI being the junior party in interference bears the burden of proving priority of invention by a preponderance of the evidence. 37 C.F.R. § 41.207(a).

Generally, a party may demonstrate that it was first to invent by establishing either (1) an earlier date of reduction to practice, or (2) an earlier date of conception, but a later date of reduction to practice, coupled with a reasonable diligence to a reduction to practice from (a) a time prior to the opponent's conception until (b) the party's reduction to practice is achieved. *Eaton v. Evans*, 204 F.3d 1094, 1097 (Fed. Cir. 2000); *Mahurkar v. C. R. Bard, Inc.*, 79 F.3d 1572,

1577 (Fed. Cir. 1996). ARTI's motion for judgment on priority alleges earlier reduction to practice and appears to allege an earlier date of conception with diligence to a later reduction to practice. (Paper 83, 1:13-23 and 17:20-22). We analyze ARTI's contentions below and, for reasons of convenience, begin with ARTI's alleged conception.

A. Conception

1. Legal Principles

Conception is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). The Federal Circuit has indicated that one way to distinguish a "bare hope" from a "complete conception" is to focus "on whether the inventors had a reasonable expectation that they would produce the claimed invention." *Hitzeman v. Rutter*, 243 F.3d 1345, 1358 (Fed. Cir. 2001). Furthermore "[c]onception of a substance claimed *per se* without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties." *Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993).

Because conception is a mental act, an inventor's testimony, standing alone, is insufficient -- some form of corroboration must be shown. *Price v. Symsek*, 988 F.2d 1187, 1194 (Fed. Cir. 1993). We apply a "rule of reason" analysis to determine whether the inventor's prior conception testimony has been corroborated.

2. Dr. Kwon Conceived of the Invention By No Later than January 15, 1992

ARTI has demonstrated that Dr. Kwon conceived of an embodiment within the scope of Count 1 by no later than January 15, 1992. Specifically, the count encompasses a purified polypeptide comprising the extracellular domain of H4-1BB. Dr. Kwon testifies that by mid-1990 he was pursuing the human homologue of mouse 4-1BB. (AX 2107, ¶ 13). Dr. Kwon testifies that he appreciated in 1991-92 that H4-1BB was a receptor protein and that the portion residing outside the cell membrane, the extracellular domain, was important to its function. (*Id.*, ¶ 40). Dr. Kwon further testifies that he instructed a visiting scientist, Dr. Kim, to prepare a construct for making a fusion protein comprising the extracellular domain of H4-1BB using specific primers Dr. Kwon had identified. (*Id.*, ¶¶ 36-38). Dr. Kwon's testimony is consistent with his contemporaneous notes and is corroborated by Dr. Kim's testimony (AX 2122). Dr. Kim testifies that he produced the requested H4-1BB fusion protein as is evidenced by Dr. Kim's notebook page dated January 15, 1992 (AX 2125). Dr. Riley testifies that a person of ordinary skill in the art would have understood that Dr. Kwon had isolated the full length H4-1BB cDNA and possessed the complete nucleic acid sequence encoding H4-1BB by at least January 7, 1992. (AX 2117, ¶¶ 31 and 41-44). Based on the evidence presented we hold that ARTI has presented corroborated evidence of a conception of an embodiment within the scope of Count 1 by no later than January 15, 1992.

B. Actual Reduction to Practice

ARTI contends that Dr. Kwon reduced the entire H4-1BB nucleotide sequence to practice by no later than December 20, 1991 and that this constitutes an actual reduction to practice of the Count. (Paper 83, 1:14-15 and 25:9-11). Further, as an alternative, ARTI contends that Dr. Kwon reduced the invention to practice by no later than January 15, 1992. (*Id.*, 25: 22-23).

1. Legal Principles

Whether an actual reduction to practice has been achieved is a question of law which is resolved on the basis of underlying facts. *Estee Lauder, Inc. v. L'Oreal*, S.A., 129 F.3d 588, 592 (Fed. Cir. 1997). Specifically, in an interference proceeding, a party seeking to establish an actual reduction to practice must satisfy a two-prong test: (1) the party constructed an embodiment that met every limitation of the interference count, and (2) the embodiment operated for its intended purpose. *Eaton*, 204 F.3d at 1097. As to the second prong, there must be some recognition of successful testing prior to the critical date for an invention to be reduced to practice. Thus, an actual reduction to practice "does not occur until an inventor, or perhaps his agent, knows that the invention will work for its intended purpose." *Estee Lauder* at 593. Furthermore, evidence of any utility is sufficient when the count does not recite any particular utility. *Nelson v. Bowler*, 626 F.2d 853, 856 (CCPA 1980).

2. ARTI Has Failed to Present Sufficient Evidence of Successful Testing to Demonstrate its H4-1BB Operated for a Practical Utility

ARTI contends that Dr. Kwon's isolation and purification of the entire

nucleotide sequence encoding H4-1BB represents an actual reduction to practice of Count 1. (Paper 83, 25:9-11). ARTI also contends that Dr. Kwon had reduced the invention to practice by January 15, 1992, when Dr. Kim had made the fusion protein that contained the extracellular portion of the H4-1BB polypeptide. (Paper 83, 25:22-23).

ARTI has failed to demonstrate with credible and corroborated evidence that its H4-1BB polypeptide or H4-1BB cDNA was shown to work for a particular utility. Specifically, ARTI has not provided evidence of successful testing prior to the critical date that establishes that the H4-1BB polypeptide or cDNA worked for a practical utility and that the utility was recognized and appreciated.

ARTI citation of Dr. Kim's production of a fusion protein containing the H4-1BB extracellular domain also fails to demonstrate an actual reduction to practice of the invention. The formation of a fusion protein containing the H4-1BB extracellular domain does not, by and of itself, establish an appreciation and recognition of successful testing for a practical utility. *Cf.*, *Cross v. Iizuka*, 753 F.2d 1040, 1044 (Fed. Cir. 1985)(pharmacological activity for a compound of the count rather than the mere existence of the compound itself was necessary to establish practical utility).

Additionally, Dr. Kwon testifies that after cloning the H4-1BB he used cDNA to study transcription of human 4-1BB in cells, generated antibodies selective for the H4-1BB extracellular domain and conducted H4-1BB ligand binding studies. (AX 2107, ¶¶ 50-52). ARTI however, does not identify evidence to corroborate Dr. Kwon's testimony regarding these experiments, the success or failure of the experiments or identify the dates the experiments were conducted. We hold that there is insufficient evidence of record to support ARTI's alleged actual reduction to practice.

C. Diligence

ARTI states that after the successful cloning of H4-1BB, Dr. Kwon continued to work diligently on his H4-1BB project up until the time he filed the '796 application on September 16, 1993. (Paper 83, 17:14-22).

1. Legal Principles

The reasonable diligence standard "balances the interest in rewarding and encouraging invention with the public's interest in the earliest possible disclosure of innovation." *Griffith v. Kanamaru*, 816 F.2d 624, 626 (Fed. Cir. 1987). Merely asserting diligence is not enough, the party chargeable with diligence must account for the entire period during which diligence is required, or provide a compelling reason to excuse the failure to take action. *Id.* at 626. Testimonial evidence by the inventor or inventors must be adequately corroborated. If documentary evidence is relied on to establish reasonable diligence, it must show specific acts at specific times directed towards an actual or constructive reduction to practice of the invention of the count. *Naber v. Cricchi*, 567 F.2d 382, 386 (CCPA 1977).

2. ARTI Has Failed to Provide Sufficient Evidence of Diligence For the Entire Period During Which Diligence Was Required

Dr. Kwon states that he was diligently working on his H4-1BB projects up until the '796 application was filed. Dr. Kwon however, does not provide specific details regarding his H4-1BB activities up until September 1993 other than generally state that during the winter of 1992-93 he began drafting a manuscript that discussed the isolation of H4-1BB cDNA. Even if Dr. Kwon's manuscript work were corroborated and accounted for the entire winter of 1992-93, Dr.

Kwon's manuscript work does not establish diligence towards a reduction to practice from spring 1993 until his constructive reduction to practice in September 1993. Additionally, although Dr. Kwon generally states that he studied H4-1BB in t-cells, generated antibodies and studied H4-1BB ligand binding, Dr. Kwon does not identify dates for these activities nor identify corroborating evidence to support his testimony on these points. We hold that ARTI has failed to provide a sufficient showing of corroborated acts at specific times over the entire period for which ARTI was accountable.

IV. Conclusion

We hold that there is insufficient evidence of record to establish that ARTI had an earlier actual reduction to practice or had an earlier date of conception coupled with reasonable diligence towards its constructive reduction to practice on September 16, 1993. We deny junior party ARTI's motion for priority and we dismiss senior party Immunex's motion for priority as moot. Judgment on priority will be entered concurrent with this decision in a separate paper against junior party ARTI.

V. ORDER

Upon consideration of the motions, and for the reasons given, it is:

Ordered that ARTI Motion for Priority is denied.

Further Ordered that Immunex Motion for Priority is dismissed.

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